

**§ 182.8988 Zinc gluconate.**(a) *Product.* Zinc gluconate.(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.**§ 182.8991 Zinc oxide.**(a) *Product.* Zinc oxide.(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.**§ 182.8994 Zinc stearate.**(a) *Product.* Zinc stearate prepared from stearic acid free from chickedema factor.(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.**§ 182.8997 Zinc sulfate.**(a) *Product.* Zinc sulfate.(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.**PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE****Subpart A—General Provisions**

Sec.

184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

**Subpart B—Listing of Specific Substances Affirmed as GRAS**

184.1005 Acetic acid.  
 184.1007 Aconitic acid.  
 184.1009 Adipic acid.  
 184.1011 Alginic acid.  
 184.1012  $\alpha$ -Amylase enzyme preparation from *Bacillus stearothermophilus*.  
 184.1021 Benzoic acid.  
 184.1024 Bromelain.  
 184.1025 Caprylic acid.  
 184.1027 Mixed carbohydrase and protease enzyme product.  
 184.1033 Citric acid.  
 184.1034 Catalase (bovine liver).  
 184.1061 Lactic acid.  
 184.1063 Enzyme-modified lecithin.  
 184.1065 Linoleic acid.  
 184.1069 Malic acid.

184.1077 Potassium acid tartrate.  
 184.1081 Propionic acid.  
 184.1090 Stearic acid.  
 184.1091 Succinic acid.  
 184.1095 Sulfuric acid.  
 184.1097 Tannic acid.  
 184.1099 Tartaric acid.  
 184.1101 Diacetyl tartaric acid esters of mono- and diglycerides.  
 184.1115 Agar-agar.  
 184.1120 Brown algae.  
 184.1121 Red algae.  
 184.1133 Ammonium alginate.  
 184.1135 Ammonium bicarbonate.  
 184.1137 Ammonium carbonate.  
 184.1138 Ammonium chloride.  
 184.1139 Ammonium hydroxide.  
 184.1140 Ammonium citrate, dibasic.  
 184.1141a Ammonium phosphate, monobasic.  
 184.1141b Ammonium phosphate, dibasic.  
 184.1143 Ammonium sulfate.  
 184.1148 Bacterially-derived carbohydrase enzyme preparation.  
 184.1150 Bacterially-derived protease enzyme preparation.  
 184.1155 Bentonite.  
 184.1157 Benzoyl peroxide.  
 184.1165 n-Butane and iso-butane.  
 184.1185 Calcium acetate.  
 184.1187 Calcium alginate.  
 184.1191 Calcium carbonate.  
 184.1193 Calcium chloride.  
 184.1195 Calcium citrate.  
 184.1199 Calcium gluconate.  
 184.1201 Calcium glycerophosphate.  
 184.1205 Calcium hydroxide.  
 184.1206 Calcium iodate.  
 184.1207 Calcium lactate.  
 184.1210 Calcium oxide.  
 184.1212 Calcium pantothenate.  
 184.1221 Calcium propionate.  
 184.1229 Calcium stearate.  
 184.1230 Calcium sulfate.  
 184.1240 Carbon dioxide.  
 184.1245 Beta-carotene.  
 184.1250 Cellulase enzyme preparation derived from *Trichoderma longibrachiatum*.  
 184.1257 Clove and its derivatives.  
 184.1259 Cocoa butter substitute.  
 184.1260 Copper gluconate.  
 184.1261 Copper sulfate.  
 184.1262 Corn silk and corn silk extract.  
 184.1265 Cuprous iodide.  
 184.1271 L-Cysteine.  
 184.1272 L-Cysteine monohydrochloride.  
 184.1277 Dextrin.  
 184.1278 Diacetyl.  
 184.1282 Dill and its derivatives.  
 184.1287 Enzyme-modified fats.  
 184.1293 Ethyl alcohol.  
 184.1295 Ethyl formate.  
 184.1296 Ferric ammonium citrate.  
 184.1297 Ferric chloride.  
 184.1298 Ferric citrate.  
 184.1301 Ferric phosphate.  
 184.1304 Ferric pyrophosphate.

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184.1307	Ferric sulfate.	184.1555	Rapeseed oil.
184.1307a	Ferrous ascorbate.	184.1560	Ox bile extract.
184.1307b	Ferrous carbonate.	184.1563	Ozone.
184.1307c	Ferrous citrate.	184.1583	Pancreatin.
184.1307d	Ferrous fumarate.	184.1585	Papain.
184.1308	Ferrous gluconate.	184.1588	Pectins.
184.1311	Ferrous lactate.	184.1595	Pepsin.
184.1315	Ferrous sulfate.	184.1610	Potassium alginate.
184.1316	Ficin.	184.1613	Potassium bicarbonate.
184.1317	Garlic and its derivatives.	184.1619	Potassium carbonate.
184.1318	Glucono delta-lactone.	184.1622	Potassium chloride.
184.1321	Corn gluten.	184.1625	Potassium citrate.
184.1322	Wheat gluten.	184.1631	Potassium hydroxide.
184.1323	Glyceryl monooleate.	184.1634	Potassium iodide.
184.1324	Glyceryl monostearate.	184.1635	Potassium iodate.
184.1328	Glyceryl behenate.	184.1639	Potassium lactate.
184.1329	Glyceryl palmitostearate.	184.1643	Potassium sulfate.
184.1330	Acacia (gum arabic).	184.1655	Propane.
184.1333	Gum ghatti.	184.1660	Propyl gallate.
184.1339	Guar gum.	184.1666	Propylene glycol.
184.1343	Locust (carob) bean gum.	184.1670	Propylparaben.
184.1349	Karaya gum (sterculia gum).	184.1676	Pyridoxine hydrochloride.
184.1351	Gum tragacanth.	184.1685	Rennet (animal-derived) and chymosin preparation (fermentation-de- rived).
184.1355	Helium.	184.1695	Riboflavin.
184.1366	Hydrogen peroxide.	184.1697	Riboflavin-5'-phosphate (sodium).
184.1370	Inositol.	184.1698	Rue.
184.1372	Insoluble glucose isomerase enzyme preparations.	184.1699	Oil of rue.
184.1375	Iron, elemental.	184.1702	Sheanut oil.
184.1386	Isopropyl citrate.	184.1721	Sodium acetate.
184.1387	Lactase enzyme preparation from <i>Candida pseudotropicalis</i> .	184.1724	Sodium alginate.
184.1388	Lactase enzyme preparation from <i>Kluyveromyces lactis</i> .	184.1733	Sodium benzoate.
184.1400	Lecithin.	184.1736	Sodium bicarbonate.
184.1408	Licorice and licorice derivatives.	184.1742	Sodium carbonate.
184.1409	Ground limestone.	184.1751	Sodium citrate.
184.1415	Animal lipase.	184.1754	Sodium diacetate.
184.1420	Lipase enzyme preparation derived from <i>Rhizopus niveus</i> .	184.1763	Sodium hydroxide.
184.1425	Magnesium carbonate.	184.1764	Sodium hypophosphite.
184.1426	Magnesium chloride.	184.1768	Sodium lactate.
184.1428	Magnesium hydroxide.	184.1769a	Sodium metasilicate.
184.1431	Magnesium oxide.	184.1784	Sodium propionate.
184.1434	Magnesium phosphate.	184.1792	Sodium sesquicarbonate.
184.1440	Magnesium stearate.	184.1801	Sodium tartrate.
184.1443	Magnesium sulfate.	184.1804	Sodium potassium tartrate.
184.1443a	Malt.	184.1807	Sodium thiosulfate.
184.1444	Maltodextrin.	184.1835	Sorbitol.
184.1445	Malt syrup (malt extract).	184.1845	Stannous chloride (anhydrous and dihydrated).
184.1446	Manganese chloride.	184.1848	Starter distillate.
184.1449	Manganese citrate.	184.1851	Stearyl citrate
184.1452	Manganese gluconate.	184.1854	Sucrose.
184.1461	Manganese sulfate.	184.1857	Corn sugar.
184.1472	Menhaden oil.	184.1859	Invert sugar.
184.1490	Methylparaben.	184.1865	Corn syrup.
184.1498	Microparticulated protein product.	184.1866	High fructose corn syrup.
184.1505	Mono- and diglycerides.	184.1875	Thiamine hydrochloride.
184.1521	Monosodium phosphate derivatives of mono- and diglycerides.	184.1878	Thiamine mononitrate.
184.1530	Niacin.	184.1890	$\alpha$ -Tocopherols.
184.1535	Niacinamide.	184.1901	Triacetin.
184.1537	Nickel.	184.1903	Tributyrin.
184.1538	Nisin preparation.	184.1911	Triethyl citrate.
184.1540	Nitrogen.	184.1914	Trypsin.
184.1545	Nitrous oxide.	184.1923	Urea.
184.1553	Peptones.	184.1924	Urease enzyme preparation from <i>Lactobacillus fermentum</i> .
		184.1930	Vitamin A.

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- 184.1945 Vitamin B<sub>12</sub>.
- 184.1950 Vitamin D.
- 184.1973 Beeswax (yellow and white).
- 184.1976 Candelilla wax.
- 184.1978 Carnauba wax.
- 184.1979 Whey.
- 184.1979a Reduced lactose whey.
- 184.1979b Reduced minerals whey.
- 184.1979c Whey protein concentrate.
- 184.1983 Bakers yeast extract.
- 184.1984 Zein.
- 184.1985 Aminopeptidase enzyme preparation derived from *lactococcus lactis*.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14653, Mar 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 184 appear at 66 FR 56035, Nov. 6, 2001, 66 FR 66742, Dec. 27, 2001, 68 FR 15355, Mar. 31, 2003, and 69 FR 13717, Mar. 24, 2004.

### Subpart A—General Provisions

#### § 184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

(a) The direct human food ingredients listed in this part have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed. The regulations in this part shall sufficiently describe each ingredient to identify the characteristics of the ingredient that has been affirmed as GRAS and to differentiate it from other possible versions of the ingredient that have not been affirmed as GRAS. Ingredients affirmed as GRAS in this part are also GRAS as indirect human food ingredients, subject to any limitations prescribed in parts 174, 175, 176, 177, 178 or § 179.45 of this chapter or in part 186 of this chapter. The purity specifications in this part do not apply when the ingredient is used in indirect applications. However, when used in indirect applications, the ingredient must be of a purity suitable for its intended use in accordance with § 170.30(h)(1) of this chapter.

(b) Any ingredient affirmed as GRAS in this part shall be used in accordance with current good manufacturing practice. For the purpose of this part, current good manufacturing practice includes the requirements that a direct human food ingredient be of appropriate food grade; that it be prepared

and handled as a food ingredient; and that the quantity of the ingredient added to food does not exceed the amount reasonably required to accomplish the intended physical, nutritional, or other technical effect in food.

(1) If the ingredient is affirmed as GRAS with no limitations on its conditions of use other than current good manufacturing practice, it shall be regarded as GRAS if its conditions of use are consistent with the requirements of paragraph (b), (c), and (d) of this section. When the Food and Drug Administration (FDA) determines that it is appropriate, the agency will describe one or more current good manufacturing practice conditions of use in the regulation that affirms the GRAS status of the ingredient. For example, when the safety of an ingredient has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the ingredient, one or more of these limited conditions of use, which may include the category of food(s), the technical effect(s) or functional use(s) of the ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, that use of the ingredient may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that that use is GRAS or shall use the ingredient in accordance with a food additive regulation. Persons seeking FDA approval of an independent determination that a use of an ingredient is GRAS may submit a GRAS petition in accordance with § 170.35 of this chapter.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food only within such limitation(s), including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(3) If the ingredient is affirmed as GRAS for a specific use, without a general evaluation of use of the ingredient, other uses may also be GRAS.

(c) The listing of a food ingredient in this part does not authorize the use of such substance in a manner that may lead to deception of the consumer or to any other violation of the Federal Food, Drug, and Cosmetic Act (the Act).

(d) The listing of more than one ingredient to produce the same technological effect does not authorize use of a combination of two or more ingredients to accomplish the same technological effect in any one food at a combined level greater than the highest level permitted for one of the ingredients.

(e) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will concurrently propose a separate regulation covering such use of the ingredient under part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(f) The label and labeling of the ingredient and any intermediate mix of the ingredient for use in finished food shall bear, in addition to the other labeling required by the Act:

(1) The name of the ingredient, except where exempted from such labeling in part 101 of this chapter.

(2) A statement of concentration of the ingredient in any intermediate mix; or other information to permit a

food processor independently to determine that use of the ingredients will be in accordance with any limitations and good manufacturing practice guidelines prescribed.

(3) Adequate directions for use to provide a final food product that complies with any limitations prescribed for the ingredient(s).

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 48 FR 48457, 48459, Oct. 19, 1983; 62 FR 15110, Mar. 31, 1997]

### Subpart B—Listing of Specific Substances Affirmed as GRAS

#### § 184.1005 Acetic acid.

(a) Acetic acid (C<sub>2</sub>H<sub>4</sub>O<sub>2</sub>, CAS Reg. No. 64-19-7) is known as ethanoic acid. It occurs naturally in plant and animal tissues. It is produced by fermentation of carbohydrates or by organic synthesis. The principal synthetic methods currently employed are oxidation of acetaldehyde derived from ethylene, liquid phase oxidation of butane, and reaction of carbon monoxide with methanol derived from natural gas.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 8, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(c) The ingredient is used as a curing and pickling agent as defined in § 170.3(o)(5) of this chapter; flavor enhancer as defined in § 170.3(o)(11) of this chapter; flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; as a solvent and vehicle as defined in § 170.3(o)(27) of this chapter; and as a boiler water additive complying with § 173.310 of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum